LEGISLATIVE SERVICES AGENCY
OFFICE OF FISCAL AND MANAGEMENT ANALYSIS

301 State House
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FISCAL IMPACT STATEMENT

LS 6094 **DATE PREPARED:** Apr 6, 1999
BILL NUMBER: SB 10 **BILL AMENDED:** Mar 29, 1999

SUBJECT: Generic Drug Substitutions.

FISCAL ANALYST: Alan Gossard
PHONE NUMBER: 233-3546

FUNDS AFFECTED: X **GENERAL** **IMPACT:** State
DEDICATED
X **FEDERAL**

Summary of Legislation: (Amended) This bill requires the Medicaid program to cover certain legend drugs that are recommended by the Drug Utilization Review (DUR) Board.

Except as provided by other laws, the bill also requires a legend drug be dispensed with the drug product specified on the prescription or drug order or by authorization of the practitioner. The bill specifies that a "generically equivalent drug product" means a multiple source drug product containing identical active ingredients. It also prohibits dispensing a legend drug except as provided in the Legend Drug Act. The bill also requires that only generically equivalent drug products may be substituted under the Generic Drugs Law.

This bill also adds advanced practice nurses to the definition of "practitioner" in the Generic Drugs Law. A pharmacist is required by the bill to inform the customer when a generic substitution is made. It also repeals the definition of "chemically equivalent drug products". (The introduced version of this bill was drafted by the Interim Study Committee on Health Issues.)

Effective Date: (Amended) Upon Passage; July 1, 1999.

Explanation of State Expenditures: (Revised) This bill requires that the Medicaid Program and the program's agents, contractors, and vendors provide coverage and reimbursement for outpatient single source legend drugs based on the recommendations of the Drug Utilization Review (DUR) Board. It is LSA's opinion that the current DUR statute (IC 12-15-35) essentially provides for these same requirements. Consequently, this provision of the bill does not represent an additional fiscal impact to the state.

Although there may be additional costs to the Medicaid Program for drugs provided through a Medicaid managed care organization due to the provision that only the DUR Board may establish a Medicaid outpatient drug formulary (rather than the unilateral establishment of the formulary by a managed care organization), any additional costs to the state are attributable to the current state DUR statute, federal statutes, and regulations and **not** to the provisions of this bill. According to the Health Care Financing Administration

(HCFA), the specific exemption allowed Medicaid managed care organizations under the federal drug rebate statute applies only to rebates and not to the establishment of drug formularies. Consequently, a Medicaid managed care organization may not establish a drug formulary unless the formulary was approved by the state DUR Board (as required by both current state statute and the amendment). Thus, any fiscal impact is attributable to current state and federal statutes, and not the provisions of this bill.

Explanation of State Revenues: (Revised) See Explanation of State Expenditures, above, regarding costs in the Medicaid Program, a program cost-shared with the federal government.

Explanation of Local Expenditures:

Explanation of Local Revenues:

State Agencies Affected: Office of Medicaid Policy and Planning

Local Agencies Affected:

Information Sources: Larry Reed, Health Care Financing Administration, (410) 786-3325.